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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,680	04/03/2001	Gary L. Cantrell	1159 WO/US	5898

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,680

Applicant(s)

CANTRELL, GARY L.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Response to Amendment

The amendment filed 12/27/2002 has been entered. Claim 7 has been amended.

Any previous rejections that are not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Unger (US 5,585,112), for the reasons set forth in the office mailed 8/29/2002.

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Klaveness (US 5,536,490), for the reasons set forth in the office mailed 8/29/2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of by Unger (US 5,585,112) or Klaveness (US 5,536,490), for the reasons set forth in the office mailed 8/29/2002.

Response to Arguments

Applicant's arguments filed 12/27/2002 have been fully considered but they are not persuasive.

Applicant asserts that Klaveness discloses microbubbles of an amphiphilic material, which are crosslinked to increase shell stability, and thus teaches away from using simple mixed length

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amphiphiles. Applicant further asserts, that, in contrast to Klaveness, with the instant invention, crosslinking is not necessary and is undesirable.

This is not found persuasive because the fact that the amphiphiles are crosslinkable does not teach away from using a blend of mixed length amphiphiles, as clearly taught in column 4 (note the amphiphiles contain 10-30 carbon atoms). There is no such teaching away in Klaveness, for example, that because the amphiphiles are crosslinked, they have to be of the same length. The instant claims do not exclude amphiphiles that have been crosslinked or polymerized. The claims only require that the shell is made of a blend of bipolar compounds having intermolecular hydrophobic regions of mixed carbon chain length (e.g., mixed carbon-chain length amphiphiles). This recitation encompasses the amphiphiles disclosed by Klaveness, whether or not they are crosslinked. In fact, Klaveness teaches amphiphilic compounds which are the same as those claimed. The claims do not have any limitations to exclude crosslinked or crosslinkable amphiphiles as disclosed by Klaveness. Further, Klaveness teaches vesicles which may or may not be crosslinked, (e.g., only that they are capable of being crosslinked, i.e., crosslinkable). Klaveness teaches microbubbles that have not been crosslinked, see column 1, lines 60-65 and example 4.

Applicant asserts that the shell design of Unger differs from that of the instant invention because Unger incorporates gas within a multilamellar shell (gas-filled liposomes).

This is not found persuasive because there are no limitations in the claims, which exclude a multilamellar shell, or liposomes from the microbubbles as claimed. The claims only require certain amphiphilic materials, and Unger discloses such materials, namely bipolar compounds having intermolecular hydrophobic regions. Unger discloses charged lipids and the like, which are within the scope of the shell forming materials as claimed. Further, contrary to applicant's assertion, Unger does disclose vesicles which may be formed as a monolayer, see column 21, lines 1-2.

Applicant asserts that Unger clearly prefers liposomes as shown in Figure 1 and also requires specialized procedures and equipment for preparing the liposomes which are not required with the claimed invention (e.g., not filtration is necessary).

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First, the claims do not exclude liposomes. Second, Unger does teach that the vesicles may be in a monolayer and disclosed examples and preferred embodiments do not constitute a teaching which is away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 169 USPQ 423 (CCPA 1971). With regard to the procedures and equipment used in the making the microbubbles disclosed by Unger, it is not seen how this differentiates the present claims over Unger, as the instant claims fail to exclude any procedures and/or equipment which may be used in the making of the microbubbles as claimed. There is nothing to exclude filtration in the instant claims. Further, Unger teaches various methods may be employed for making the microbubbles, see columns 9-12.

Applicant asserts that the acoustic properties of the claimed microbubbles are better than those of Unger.

This appears to assert unexpected results; however, this is not found persuasive because, some claims have been rejected over Unger under 35 USC 102, which cannot be overcome by unexpected results. Also, the asserted results neither show a side-by-side comparison with Unger or show results which are commensurate in scope with the claimed invention, as the shell material claimed is broad, having a shell of a blend of bipolar compounds having intermolecular hydrophobic regions of mixed carbon length, which encompasses many amphiphilic materials.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read "Michael G. Hartley", with a stylized flourish at the end.

Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
February 14, 2003